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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,027	08/27/2003	Fred H. Burbank	R0367.00302	6463

7590 03/28/2007
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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/650,027

Applicant(s)

BURBANK ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30, 32, 33, 35-38, 40-54 and 56-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30, 32, 33, 35-38, 40-54 and 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2007 has been entered.

Allowable Subject Matter

2. The indicated allowability of claims 28-30, 32, 33, 35-38, 40-54 and 56-64 is withdrawn in view of the newly discovered reference(s) to Burbank et al (6,471,700 B1). Rejections based on the newly cited reference(s) follow.

Specification

3. The disclosure is objected to because of the following informalities: The specification pages have no page numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 28, 32, 33, 38, 42, 45-48, 51-54, 58, 59, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Burbank et al (6,471,700 B1)

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Burbank et al disclose a biopsy system and further disclose an elongate cannula having a longitudinal axis, an open distal end with a transverse dimension perpendicular to the longitudinal axis, a proximal end and an inner lumen extending to and in fluid communications with the open distal end; a first tissue cutting element disposed on the open distal end of the cannula and lies in a plane traversing the longitudinal axis of the cannula; a stylet slidably disposed at least in part within the inner lumen, configured for axial translation between a withdrawn position and an extended position and which has a distal end having a transverse dimension perpendicular to the longitudinal axis of the cannula and has a distal portion with an outer diameter that is greater than the inner

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diameter of the open distal end of the cannula; a second tissue cutting element comprising an electrosurgical cutting surface, disposed on the distal end of the stylet; a high frequency power source and means connecting the source to the distal tissue cutting element; the distal end of the stylet comprises a hemispherical head and the electrosurgical cutting surface extends over the head; and a return electrode. See Figures 22 and 23; Column 5, lines 45-51; Column 13, lines 66-67; and Column 14, lines 1-23.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 29, 30, 43, 44, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,471,700 B1) as applied to claims 28, 42 and 48 above, and further in view of Milliman et al (5,817,034).

Burbank et al, as discussed above, disclose a biopsy system, but fail to disclose the first tissue cutting element has an electrosurgical cutting surface; and a source of high frequency power connected to the electrosurgical cutting surface.

Milliman et al disclose a means for removing tissue and further disclose the first tissue cutting element has an electrosurgical cutting surface; and a source of high

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frequency power connected to the electrosurgical cutting surface. See Column 9, lines 3-12; and Column 10, lines 11-21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first tissue cutting surface of Burbank et al to include an electrosurgical cutting surface, as per the teachings of Milliman et al, since it would provide a less traumatic means of severing the tissue sample from the surrounding tissue.

8. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,471,700 B1) as applied to claim 28 above, and further in view of Bryan et al (6,050,955).

Burbank et al, as discussed above, disclose a biopsy system, but fail to disclose a driving unit coupled to the stylet; and the driving unit has a translation mechanism comprising a carrier connected to the proximal portion of the stylet and movably mounted on the driving unit between a first position and a second position, and a carrier drive.

Bryan et al disclose a biopsy system and further disclose a driving unit coupled to the stylet; and the driving unit has a translation mechanism comprising a carrier connected to the proximal portion of the stylet and movably mounted on the driving unit between a first position and a second position, and a carrier drive. See Figures 18, 23, and 28.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy system of Burbank et al to include the means

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of operating the stylet as per the teachings of Bryan et al, since it would provide an automatic means of acquiring a tissue sample from the body.

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,471,700 B1) and Bryan et al (6,050,955) as applied to claim 36 above, and further in view of Voegele (6,610,020 B2).

Burbank et al and Bryan et al, as discussed above, disclose a biopsy system but fail to disclose a motor which has a drive shaft coupled to a drive screw of the carrier drive; a screw driven mechanism coupled between the drive screw and the carrier, whereby rotation of the drive screw in a first direction moves the carrier from the first position to the second position.

Voegele discloses a biopsy system and further discloses a motor which has a drive shaft coupled to a drive screw of the carrier drive; a screw driven mechanism coupled between the drive screw and the carrier, whereby rotation of the drive screw in a first direction moves the carrier from the first position to the second position. See Figures 2 and 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Burbank et al and Bryan et al to include a motorized means of operating the biopsy system, as per the teachings of Voegele, since it would provide a means of accurately obtaining a tissue specimen from surrounding tissue.

10. Claims 40, 41, 56, 57 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,471,700 B1).

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Burbank et al, as discussed above, disclose a biopsy system utilizing an electrosurgical cutting element on the distal end and the use of at least one return electrode, but not the location of the return electrode. It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the return electrode on the stylet or the cannula, since it is well known in the art to utilize a return electrode that is placed either on the body or on the surgical instrument in close proximity to the cutting element.

11. Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,471,700 B1) in view of Milliman et al (5,817,034).

Burbank et al, as discussed above, disclose a biopsy system comprising an elongate cannula having a longitudinal axis, an open distal end, a proximal end and an inner lumen extending to and in fluid communication with the open distal end; an elongate stylet disposed at least in part in the inner lumen, and configured for axial translation between a withdrawn position and an extended position; the stylet has an outer diameter that is greater than the diameter of the first tissue cutting element; and the tissue penetrating distal end of the stylet has an electrosurgical cutting element which lies in a plane parallel with the longitudinal axis of the cannula. See Figures 22 and 23; Column 5, lines 45-51; Column 13, lines 66-67; and Column 14, lines 1-23.

Burbank et al however fail to disclose an electrosurgical cutting element located at the open distal end of the cannula and lies in a plane traversing the longitudinal axis of the cannula.

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Milliman et al, as discussed above, disclose a means for removing tissue and further disclose an electrosurgical cutting element located at the open distal end of the cannula and lies in a plane traversing the longitudinal axis of the cannula. See Column 9, lines 3-12; and Column 10, lines 11-21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first tissue cutting element of Burbank et al to include the use of an electrosurgical cutting element, as per the teachings of Milliman et al, since it would provide a means of removing a tissue sample from surrounding tissue in a less traumatic means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

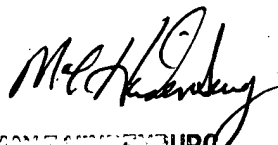
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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